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Using Reverse Payment Agreements as an Effective Way to Maintain a Patent Monopoly in ihe Pharmaceutical Industry

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USING REVERSE PAYMENT AGREEMENTS AS AN EFFECTIVE WAY TO MAINTAIN A PATENT MONOPOLY IN THE PHARMACEUTICAL INDUSTRY

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I. INTRODUCTION

Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) to help lower the cost of drugs for the public and to encourage investment in research and development of new drugs.[1] The Hatch-Waxman Act was a compromise that aimed to fulfill two goals: to extend patents for name-brand (pioneer) drug companies and to ease FDA approval for generic drug companies to enter the market.[2] Decades later, commentators praise the Hatch-Waxman Act for creating the generic pharmaceutical industry.[3]

Although the purpose of the Hatch-Waxman Act was to increase competition between pioneer and generic drug companies, pioneer drug

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1. *See* Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 421 (2011) (predicting generic drugs would save American consumers $920 million).

2. *See id*. (explaining that there were 150 pioneer drugs in the market with no generic versions).

3. *See* Matthew Avery, Note, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 175-76 (2008) (detailing that the Act also ensured the quality of generic drugs and eliminated research costs for duplicate clinical trials).

companies began making settlements with generic drug companies called "reverse payment" agreements that effectively delay competition.[4] Reverse payment agreements allowed the pioneer drug company to retain its monopoly on the market by delaying generic drug entry, and thus made the Hatch-Waxman Act ineffective in bringing competition to that particular drug market.[5]

Under the Sherman Act, the antitrust analysis for patent antitrust claims is complex because the purpose of patent law—to grant a legal monopoly—contradicts the purpose of antitrust law—to prevent a monopoly.[6] To balance both laws, courts use the rule of reason analysis in patent antitrust claims to determine whether a practice or agreement that exploits the patent is an unreasonable restraint on trade.[7]

Courts were split on whether reverse payment agreements under the Hatch-Waxman Act violated the Sherman Antitrust Act and applied three different analyses to determine whether a violation had occurred.[8] Some courts followed the precedent of most Sherman Antitrust patent cases and used the general antitrust analysis of rule of reason to determine whether reverse payment agreements were an unreasonable restraint to trade.[9] Other courts held reverse payment agreements as per se illegal agreements and banned them all together.[10] Lastly, some courts moved away from both the rule of reason analysis and the per se illegal designation and instead applied a scope of the patent analysis, which permits the patent holder to maintain a monopoly on an invalid or expired patent.[11]

This Comment argues that the Supreme Court was correct in holding that

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4. *See id.* at 181 (describing the settlement between a pioneer and generic drug company that result in the generic delaying marketing of its generic equivalent until a later date).

5. *See* Kelly, *supra* note 1, at 432 (describing pioneer drug companies as "gaming" the Hatch-Waxman Act to their advantage and delaying generic drug competition).

6. *See In re* K-Dur Antitrust Litig., 686 F.3d 197, 216 (3d Cir. 2012) (recognizing that the court must proceed with caution because the patent holder possesses a legal monopoly).

7. *See* Arizona v. Maricopa Cnty. Med. Soc'y, 457 U.S. 332, 343-44 (1982) (explaining that the rule of reason requires a holistic approach that weighs all the circumstances surrounding the industry).

8. *See In re K-Dur*, 686 F.3d at 209, 210-14, 217 (describing the varying precedent from five other circuits, and applying a form of rule of reason analysis).

9. *See Maricopa Cnty. Med. Soc'y*, 457 U.S. at 343 (explaining the rule of reason is the predominantly used analysis for antitrust cases).

10. *See In re K-Dur*, 686 F.3d at 210-11 (surmising per se illegal designation broadly dismisses reverse payment agreements).

11. *See id.* at 212-13 (describing the Second Circuit's denial of an antitrust claim over a reverse payment agreement that occurred after the patent was found invalid).

the rule of reason analysis is the best analysis for reverse payment agreements because the scope of the patent and per se illegal analyses do not provide a balance between patent and antitrust interests.[12] Part II examines the process of FDA drug approval and the two antitrust analyses that are applied to antitrust claims.[13] Part II also discusses the varying antitrust analyses that courts have applied to reverse payment agreements and the most recent case of *In re K-Dur*.[14] Part III argues that the Supreme Court was correct to adopt the rule of reason analysis for reverse payment antitrust claims because the rule of reason provides the best inquiry that incorporates both patent and antitrust law.[15] Part III also reviews the faults of applying the per se illegal and the scope of the patent analyses and argues that these tests do not provide the proper balance between patent and antitrust laws.[16] Part IV offers policy arguments against reverse payment agreements.[17] Finally, Part V of this Comment concludes that by applying the rule of reason, courts will be able to consistently apply antitrust laws to reverse payment antitrust litigation.[18]

II. BACKGROUND

A. How the Hatch-Waxman Act Opened the Market to Generic Drug Manufacturers

The new drug approval process is a long and costly venture, requiring the applicant to submit a New Drug Application (NDA) to the FDA that is

12. *See* FTC v. Actavis, Inc., 133 S.Ct. 2223, 2238 (2013) (holding the rule of reason applied to reverse payment agreements). The Supreme Court's decision in *Actavis* was handed down as this Comment was going to press. Though the Court's decision in regards to the application of the rule of reason is instructive when applied to reverse payment agreement cases like *In re K-Dur*, the analysis presented here will more thoroughly explore the various analyses performed by the lower courts and is still relevant to show why applying the rule of reason follows legal precedent for patent antitrust cases**.** *In re K-Dur*, 686 F.3d at 214 (concluding the scope of the patent analysis does not apply any antitrust scrutiny because the scope of the patent analysis solely focuses on the rights of the patent holder).

13. *See infra* Part II (outlining the FDA drug approval process).

14. *See infra* Part II (describing circuit precedent).

15. *See infra* Part III (arguing the rule of reason is a neutral analysis between the scope of the patent and per se illegal analyses).

16. *See infra* Part III (arguing the scope of the patent test is an insufficient antitrust analysis).

17. *See infra* Part IV (illustrating how patent drug infringement cases that settle as a result of reverse payment agreements are allowing monopolies on patents that should have been made invalid, and thus hindering competition).

18. *See infra* Part V (concluding the rule of reason provides a necessary balance between patent law and antitrust law).

comprised of preclinical and clinical data to demonstrate the safety and effectiveness of the drug for human consumption.[19] Prior to the Hatch-Waxman Act, if a generic brand was similar in effectiveness to a new drug, the FDA still required the generic manufacturer to spend millions of dollars conducting its own research and collecting data for a separate full NDA.[20]

The Hatch-Waxman Act opened the door to generic drug manufacturers by shortening the process and reducing FDA approval costs.[21] The full NDA requirement was changed to an Abbreviated New Drug Application (ANDA) that allowed a bioequivalent generic drug to gain approval merely by demonstrating the generic drug was as safe and effective as the original drug.[22] In addition to filing the ANDA, the applicant must certify the application under a paragraph IV, which declares that the new drug does not infringe any patent listed with the FDA.[23] When a generic manufacturer submits a paragraph IV certification, it must send notice to each listed patent owner impacted.[24] Upon filing the ANDA and the certification, the patent holder has forty-five days to initiate an infringement suit against the applicant.[25] Upon the filing of an infringement suit, an automatic stay will prevent the FDA from approving the generic drug until the earlier of thirty months or a court hearing that finds the patent has not been infringed or is invalid.[26] At the dismissal of the automatic stay and upon the approval by the FDA, the generic brand receives a 180-day exclusivity period where it is the only generic manufacturer that can market the product.[27] Only the first generic

19. *See* Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 801 (D.C. Cir. 2001) (declaring "[a]n NDA is time consuming and costly to prepare"); *see also* Kelly, *supra* note 1, at 420 (describing the paperwork for an NDA and describing that generic drug applicants do not have to apply for similar drug approval).

20. *See* Kelly, *supra* note 1, at 420-22 (explaining the cost of clinical trials was a major hindrance to generic manufacturers).

21. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1565 (2006) (reporting the cost for an Abbreviated New Drug Application (ANDA) reduced the cost of FDA approval from over two hundred million dollars to one million dollars).

22. *See* Kelly, *supra* note 1, at 420-21 (explaining the retesting of the generic drug was also found unethical because it required that some patients receive placebos and not effective treatment).

23. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012) ("[Su]ch patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted[.]").

24. *See id.* § 355(j)(2)(B)(iii)(I) (requiring notice to each patent owner that is subject to the certification).

25. *See id.* § 355(j)(5)(B)(iii).

26. *See id.*

27. *See id.* § 355(j)(5)(B)(iv).

manufacturer who submits a paragraph IV certification receives the exclusivity period, and they may use it at their sole discretion.[28]

Theoretically, the Hatch-Waxman Act would allow generic manufacturers to spend fewer resources to enter the market.[29] However, in actuality, pioneer manufacturers were taking advantage of the Hatch-Waxman Act to delay product release through agreements made between them and generic manufacturers.[30] A generic manufacturer that filed an ANDA would eventually settle the patent infringement suit with the pioneer manufacturer and agree to not market its product in return for payment.[31] These settlements became known as reverse payment agreements.[32] The agreements often required that the generic manufacturer maintain its 180-day exclusion right to bar the FDA from approving other generic drugs of the same bioequivalence.[33] This allowed the pioneer drug company to maintain a de facto monopoly on the market beyond the patent expiration.[34] Reverse payment agreements eventually caught the attention of Congress, prompting it to change the statute to require that drug companies file the settlement agreements for review of possible antitrust issues.[35]

B. Standard Antitrust Scrutiny

Antitrust law stems from the Sherman Act that forbids any contract or agreement that restrains trade or commerce in the United States.[36] The

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28. *See id.* § 355(j)(5)(B)(iv)(II)(bb) (describing the first applicant as the first one who submits an application containing a certification under paragraph (2)(A)(vii)(IV)).

29. *See* Kelly, *supra* note 1, at 421 (articulating the generic manufacturer could now challenge the validity of a drug patent at a reduced cost).

30. *See Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace Before the S. Comm. on the Judiciary*, 108th Cong. 4-5 (2003) [hereinafter *Judiciary*] (statement of Timothy J. Muris, Chairman, Federal Trade Commission) (arguing that reverse payment agreements were delaying generic drug entry into the market).

31. *See* Kelly, *supra* note 1, at 431 (describing the general practice uses reverse payments to delay generic drug entry into the market).

32. *See id.* (providing, as an alternative name, "pay-for-delay").

33. *See id.* (noting that generic companies agreed not to challenge the patent or market the generic in exchange for payments).

34. *See id.* (arguing that asserting its 180-day exclusion rights near the expiration of the patent allowed the pioneer company to block entry of other generic companies for at most 180 days).

35. *See id.* at 437 (explaining the 2003 Amendment to the Hatch-Waxman Act required the parties to file copies of the settlement agreement with the FTC and Department of Justice).

36. *See* 15 U.S.C. § 1 (2010) (declaring, in plain language, every contract that restrains trade or commerce amongst the states is illegal); *see also* State Oil Co. v.

statute is interpreted to outlaw only unreasonable restraints using a rule of reason analysis for most antitrust claims.[37] Under the rule of reason analysis, the court weighs a variety of factors, including specific information about the relevant business, the condition of the business before and after the restraint was imposed, and the restraint's history, nature, and effect, to determine whether the questioned practice is an unreasonable restraint on trade.[38]

Restraint of trade can be deemed unlawful per se if the court can predict the harmful anticompetitive effect of the restraint and identify only limited pro-competitive benefits.[39] Per se antitrust is applicable when the court is reasonably able to predict that the practice will restrict competition and decrease output.[40] The Supreme Court has categorized practices such as horizontal price-fixing as illegal per se because the probability of the anticompetitive nature of the practice is high.[41]

C. Hatch-Waxman Antitrust Analysis

Prior to *In re K-Dur* in the Third Circuit, sister circuits reviewed antitrust claims against reverse payment agreements and applied varying antitrust analyses, including a newly defined scope of the patent analysis that was created just for patents under the Hatch-Waxman Act.[42] The various antitrust analyses resulted in differing outcomes on the same or similar facts.[43]

Khan, 522 U.S. 3, 10 (1997) (establishing the Sherman Act as the antitrust standard).

37. *See Khan*, 522 U.S. at 10 (explaining precedent only applies rule of reason and per se illegal analyses).

38. *See* Bd. of Trade of Chi. v. United States, 246 U.S. 231, 238 (1918).

39. *See Kahn*, 522 U.S. at 10 (stating that "predictable and pernicious anticompetitive" restraints are per se illegal).

40. *See* Arizona v. Maricopa Cty. Med. Soc'y, 457 U.S. 332, 343-44 (1982) (asserting a per se illegal analysis permits courts to confidently predict that the rule of reason will condemn the restraint of trade); *see also* Broad. Music, Inc. v. Columbia Broad. Sys. Inc., 441 U.S. 1, 19-20 (1979) (concluding the blanket license did not facially appear to be one that would always or almost always tend to restrict competition and decrease output).

41. *See* NCAA v. Bd. of Regents, 468 U.S. 85, 100-01 (1984) (defining horizontal price-fixing as an agreement between competitors that sets a nonnegotiable price on a good).

42. *See In re* K-Dur Antitrust Litig., 686 F.3d 197, 210, 218 (3d Cir. 2012) (holding that the rule of reason applied); *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 907 (6th Cir. 2003) (holding per se illegal analysis applied); Valley Drug Co. v. Geneva Pharm., 344 F.3d 1294, 1310 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004) (applying the scope of the patent analysis to reverse payment agreements).

43. *Compare In re K-Dur*, 686 F.3d at 211-12 (citing *Valley Drug*, 344 F.3d at 1294) (using the rule of reason to find the reverse payment agreement between

1. Rule of Reason Analysis

In antitrust cases, courts typically apply the rule of reason analysis, which is more deferential than the per se illegal analysis.[44] Under the rule of reason, the court will look at factors such as the industry and its condition prior to and after the restraint; the nature, history, and effect of the restraint; and the purpose of the restraint intended by the actor.[45] Courts will weigh the pro-competitive effects against the anticompetitive effects to determine whether the restraint is unreasonable.[46]

In the context of a patent, the purpose of a restraint agreement becomes more influential to the fact finder because patents already provide a right to exclude, and the court will not interfere with that right.[47] The agreement and the actions of the parties to the agreement are factors to determine the actual purpose or intent of the settlement.[48] Any acts by the parties that hinder competition upon signing the settlement can disprove any original intent posed during the negotiations.[49]

2. Per Se Illegal Analysis

Certain agreements are categorized as per se illegal because their effect on competition is so harmful and without any valued benefit that they automatically violate the Sherman Act.[50] The per se illegal analysis comes

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Schering and generic brands did violate the Sherman Act), *with* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005) (holding that under the scope of the patent analysis, the reverse payment agreement between Schering and generic brand drugs did not violate the Sherman Act).

44. *See* Maricopa Cty. Med. Soc'y, 457 U.S. at 344 (explaining the per se illegal rule may invalidate some agreements that would be upheld under the rule of reason analysis).

45. *See* Bd. of Trade of Chi. v. United States, 246 U.S. 231, 238 (1918) (asserting the legality of an agreement is not a simple determination but requires the consideration of many factors).

46. *See In re-K-Dur*, 686 F.3d at 209 (providing that if the plaintiff can show the challenged conduct has anti-competitive effects on the market, then the burden to prove a sufficiently procompetitive objective shifts to the defendant).

47. *See* United States v. Singer Mfg. Co., 374 U.S. 174, 189-90 (1963) (insisting the purpose of the agreement between patent holders to exclude was within the purview of the Sherman Act).

48. *See id.* at 190-93 (holding the parties actions clearly established a concerted action to restrain trade).

49. *See id.* at 195 (questioning defendant's procompetitive objective to end litigation because defendant sued competitors on behalf of joint parties' patent's).

50. *See* Northern Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958) (explaining that agreements that have a harmful effect on competition and lack any redeeming virtue are unreasonable).

under the Sherman Act as applied by the courts.[51] The following are categorized as per se illegal: price-fixing (horizontal agreements), division of markets, group boycotts, and tying arrangements.[52]

Reverse payment agreements closely resemble price-fixing in a horizontal agreement.[53] A horizontal agreement is an agreement between direct competitors to allocate shares of the market to minimize competition.[54] Horizontal agreements usually take the form of direct competitors agreeing to set a minimum price (price-fixing) for a product in order to eliminate competition.[55]

If the practice is not clearly price-fixing, the court reviews factors to show that the practice is typically harmful to the market.[56] Especially in cases where the law allows a monopoly, the court must look at whether experience warrants classifying the type of agreement as per se illegal.[57] The court considers the special conditions surrounding the industry and determines whether the agreement or practice has some redeeming value in the context of the industry.[58] The court's analysis should account for Congress's perspective of the practice and whether adjustments to the law were created to prevent the practice.[59] When a statute provides a monopolistic industry around certain rights, the court cannot deem agreements that reasonably enforce those rights as per se illegal.[60]

Lastly, to determine whether the agreement requires per se distinction,

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51. *See id.*

52. *See id.* (finding the negative consequences of these broad activities outweighed any positive benefits that may arise).

53. *See In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 900 (6th Cir. 2003) (concluding an agreement where the pioneer drug company paid the generic drug company to delay market entry was a horizontal agreement).

54. *See* United States v. Topco Assocs., 405 U.S. 596, 608 (1972) (explaining a vertical agreement occurs when the competitors are not direct competitors or are on different levels of the market).

55. *See id.* at 611-12 (explaining that restraining competition by a private party is biased by the party's own interests, while the same restraint made by Congress evaluates the competing interests to come to a resolution that benefits society).

56. *See* Broad. Music, Inc. v. Columbia Broad. Sys. Inc., 441 U.S. 1, 9-10 (1979) (finding that two partners agreeing to a price does not always violate the Sherman Act).

57. See *id.* (explaining how conditions in copyright law are *sui generis*; thus recognizing there are particular laws created for the purpose of protecting licensing).

58. See *id.* at 14-15 (explaining that in "unique" markets the circumstances can negate a per se finding because the restraint on trade increases competition or makes it more efficient).

59. *See id.* at 15-16 (explaining that Congress created a similar copyright licensing fee scheme as the plaintiff in question indicating the scheme was pro-competitive).

60. *See id.* at 19 (explaining that copyright laws provide the owner with power to restrict use of the copyrighted material and the court must be sensitive to this fact).

the court must evaluate whether the practice facially appears to usually restrict the market and oppress market output, and whether no alternatives are available in the market.[61] If the agreement increases efficiency and market output, and there are alternative products or services in the market, the court will not use a per se illegal analysis.[62]

Once a practice is held as per se illegal, the analysis requires that the practice is automatically deemed illegal.[63] The court will not do any further review and any benefits from the practice are lost.[64] Because the per se illegal analysis is so harsh, courts are reluctant to find a per se illegal restraint and apply a per se illegal analysis.[65]

3. Scope of the Patent Analysis

The scope of the patent analysis is a new analysis created by the Eleventh Circuit that was developed because of the complexities between the legal monopolies granted by patent law and the Hatch-Waxman Act.[66] The analysis is primarily founded under patent law and is overwhelmingly in favor of the patent holder.[67] Under the scope of the patent analysis, courts have held that the pioneer manufacturer's patent gives it exclusionary rights, and the reverse payment agreement is valid if it is within those rights.[68] In one case where the Eleventh Circuit applied the scope of the patent analysis, the court gave directions to review the case in light of whether the provisions in the agreement exceeded the scope of the exclusionary rights of the patent, and upon review, determine if the acts

61. *See id.* at 19-20, 23-24 (concluding the licensing was reasonable because there were alternative licensing fees).

62. *See id.* at 20 (finding the license agreement was beneficial to the copyright market because it helped efficiency, and the plaintiff had alternatives that were not adequately sought).

63. *See* Arizona v. Maricopa Cnty. Med. Soc'y, 457 U.S. 332, 344 (1982) (describing the per se distinction as a rule of "general application").

64. *See id.* (acknowledging that the per se illegal analysis is imperfect because it invalidates practices that the rule of reason might uphold).

65. *See id.* (requiring previous court experience with the practice so that the court can confidently assume the rule of reason will find it illegal).

66. *See* Valley Drug Co. v. Geneva Pharm., 344 F.3d 1294, 1308 (11th Cir. 2003) (holding the agreement did not violate the Sherman Act because the exclusionary effect was within the patent expiration date).

67. *See In re* K-Dur Antitrust Litig., 686 F.3d 197, 214 (3d Cir. 2012) (explaining the scope of the patent analysis does not use any antitrust scrutiny and no reverse payment case has ever gone to trial).

68. *See Valley Drug*, 344 F.3d at 1306-07 (concluding that reverse payment agreements were not per se illegal when the agreement was no broader than the patent's exclusionary right).

were anticompetitive.[69]

The scope of the patent analysis favors patent law over antitrust law because it evaluates the patent monopoly as a stand-alone analysis.[70] It rejects further inquiry into the surrounding factors of the industry and precludes antitrust analysis that is generally required in patent antitrust claims.[71] The scope of the patent analysis results in the court merely basing an antitrust claim on patent law.[72] The only occasion the court found an antitrust violation under a scope of the patent analysis for a reverse payment agreement was in *Andrx Pharmaceuticals, Inc. v. Elan Corp*.[73] In *Elan Corp.*, the settlement agreement excluded the generic drug from the market beyond the patent expiration date.[74] The court found an antitrust claim in the agreement because the generic manufacturer agreed to never market the generic drug, thus giving the patent holder an unlimited patent monopoly.[75]

D. Returning to the Rule of Reason: In re K-Dur

1. Facts

The facts of this case arise from an agreement between a pioneer drug manufacturer, Schering, and generic manufacturers, Upshur and ESI.[76] Schering created K-Dur and obtained a patent on the controlled-release coating of a potassium chloride supplement that is used to treat potassium deficiencies.[77] In 1995, on separate occasions, two generic manufacturers each filed ANDAs that certified their generic drug based on a paragraph IV

69. *See id.* at 1312 (stating the prohibition of generic brands, the waiver of the 180-day exclusivity period, and other provisions require consideration under the scope of the patent).

70. *See In re K-Dur*, 686 F.3d at 214 (asserting the scope of the patent analysis improperly restricts antitrust law to instances of fraud on the Patent and Trademark Office or baseless infringement claims).

71. *See* United States v. Singer Mfg. Co., 374 U.S. 174, 196-97 (1963) (concluding antitrust law still applies to patent holders).

72. *See In re K-Dur*, 686 F.3d at 214 (noting the scope of the patent analysis is not an antitrust analysis).

73. *See* 421 F.3d 1227, 1235 (11th Cir. 2005) (holding that blocking the generic after the patent expired was beyond the scope of the patent exclusion).

74. *See id.* (narrowing the relevant market to controlled release naproxen).

75. *See id.* (explaining the agreement eliminated the competition because the defendant was the only supplier).

76. *See In re K-Dur*, 686 F.3d at 205-06 (explaining Upsher was the first generic manufacturer to file a paragraph IV certification and ESI filed months later).

77. *See id.* at 203 (noting the patent expired in September 2006).

non-infringement claim.[78] The first, Upsher, created a generic version of K-Dur, and upon defending the patent infringement claim, argued the composition of the controlled release coating in its generic version was different than Schering's.[79] The litigation ended by settlement, hours before the district court would rule on motions for summary judgment.[80] In the settlement, Upsher did not concede to the validity or the possible infringement of the patent, but agreed to delay marketing of its generic drug until September 1, 2001.[81] Interestingly, Upsher also gave a license to Schering to make and sell other drugs in exchange for payments of over sixty million dollars over three years.[82]

The second agreement between Schering was with another generic drug company, ESI, who defended the infringement suit based on their controlled release version being a multi-layered coating.[83] The patent infringement litigation ended when ESI agreed to delay marketing until 2004 in exchange for an initial payment of five million dollars and future payments contingent upon approval of ESI's ANDA.[84]

Various wholesalers and retailers who purchased K-Dur brought antitrust claims.[85] The district court held that the settlements were only subject to antitrust scrutiny if the scope of Schering's patent was exceeded or the underlying patent infringement suits were objectively baseless.[86]

2. Opinion

On appeal, the Third Circuit reversed.[87] The court rejected the scope of

78. *See id.* at 205-06 (stating that both generic companies asserted their drugs fell outside of the patent because they used different chemical compositions).

79. *See id.* at 205 (describing Upsher's characterization of the suit as "baseless").

80. *See id.* (acknowledging the settlement was prior to a patent trial, but after some litigation).

81. *See id.* (explaining Upsher would receive a non-royalty non-exclusive license to sell and make its generic drug at the conclusion of the agreement).

82. *See id.* at 205-06 (assuming the secondary purpose of the settlement was later asserted as primary reason for payment).

83. *See id.* at 206 (contrasting ESI's multi-layered coating with the patent-holder's single layered coating).

84. *See id.* (explaining ESI agreed to a royalty-free license to begin in 2004 and a contingent payment that ranged from six-hundred and twenty-five to ten million dollars for ANDA approval).

85. *See id.* at 207 (finding that purchasers who were harmed by the effect of the agreement can bring suit).

86. *See id.* at 208 (describing the special master's presumption that Schering's patent was valid and it therefore had a right to exclude or agree to settlements until the patent expired).

87. *See id.* at 218 (rebuking the district court's use of the scope of the patent

the patent analysis and held that the rule of reason should apply for reverse payment settlements.[88] In rejecting the scope of the patent analysis, the court argued that the analysis did not apply any antitrust scrutiny under the Sherman Act and was not within the purpose of the Hatch-Waxman Act.[89] Although patent law gave Schering the right to exclude others and license its K-Dur patent, the court found it improper to legally assume the underlying patent was valid when determining if the exclusionary rights of the patent extended to the settlement.[90]

Patent validity was the core of the scope of the patent analysis, but the FTC's findings challenged that assertion when the Commission reported Hatch-Waxman patent infringement suits have a seventy-three percent success rate.[91] The court concluded that a generic drug certification under paragraph IV of the Hatch-Waxman Act was likely to overturn a weak patent and open the market to competitors.[92]

Using the rule of reason, the court found a payment to a generic company prima facie evidence of a restraint to trade.[93] The large payment was given consideration for the delay and not to license other drugs as the settling parties had argued.[94] Upsher and ESI would not have delayed entering the market but for Schering paying them millions of dollars in compensation for the profit lost by not marketing their generic products.[95] Schering, Upsher, and ESI could rebut the evidence if they could show that the payment was not for delayed entry or that there was a benefit that encouraged competition.[96] Under this analysis, the court of appeals

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analysis).

88. *See id.* (adopting the quick look rule of reason in light of the "economic realities" in the industry).

89. *See id.* at 214 (dismissing the scope of the patent as contrary to a "long line of Supreme Court precedent on patent litigation and competition").

90. *See id.* (asserting that courts only assume patent validity in a procedural manner and not as a substantive right that is conclusive in the law).

91. *See* FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 16 (2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (reporting study findings from 1992 – 2002).

92. *See In re K-Dur*, 686 F.3d at 215 (arguing that the exclusionary right of the patent is less justified when a possible competitor, who can challenge the patent and possibly win, is paid off).

93. *See id.* at 218 (viewing the generic deferral date as an unreasonable litigation compromise).

94. *See id.* at 218 (concluding that the *quid pro quo* for the payment was the generic's agreement to delay marketing).

95. *See id.* at 205-06 (observing that Upsher received sixty million dollars to delay, and ESI received between six-hundred and twenty-five thousand and ten million dollars depending on FDA approval).

96. *See id.* at 218 (rejecting the defendant's argument that the payments were for

remanded the case to the district court with instructions for the defendant to provide pro-competitive justifications for the reverse payment settlements.[97]

III. ANALYSIS

The Supreme Court was correct in holding that the rule of reason analysis is the best analysis for reverse payment agreements.[98] The rule of reason should apply because patent law requires a more balanced review of patent and antitrust than the inquiry provided in the per se illegal or scope of the patent analyses.[99] On one end of the spectrum, a per se illegal analysis would completely negate reverse payment agreements regardless of their benefits to patent law.[100] On the other end, the scope of the patent analysis is one of many factors used in general antitrust analysis and fails to review the concerted actions between patent holders.[101] The rule of reason analysis does what the other two fail to do: allows a full antitrust analysis of reverse payment agreements based on the market effect of the parties' joint agreements.[102] Applying the rule of reason, the Court should hold the reverse payment agreement in *In re K-Dur* as an unreasonable restraint to trade and a violation of the Sherman Act because it intentionally eliminates competition.[103]

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licensing other drugs because the licensed drugs were subsequently abandoned).

97. *See id.* at 209, 218 (finding the plaintiff met its burden, and the burden shifted to the defendant to rebut the evidence).

98. *See* FTC v. Actavis, Inc., 133 S.Ct. 2223, 2237 (2013) (holding the rule of reason weighs the anticompetitive and pro-competitive effects of reverse payment agreements).

99. *See In re K-Dur*, 686 F.3d at 215 (explaining that patents provide a valid monopoly, and the court must evaluate the agreement based on the generic pharmaceutical industry).

100. *See* Broad. Music, Inc. v. Columbia Broad. Sys., Inc., 441 U.S. 1, 16 (1979) (explaining there was no universal consensus that blanket licensing was per se illegal as price-fixing so the facts required a rule of reason analysis to assess the claim).

101. *See* Bd. of Trade of Chi. v. United States, 246 U.S. 231, 239 (1918) (establishing the scope of monopoly as one factor).

102. *See Broad. Music, Inc.*, 441 U.S. at 9-10 (clarifying per se designation concludes inquiry while the rule of reason provides the proper background review that legal monopolies require); *In re K-Dur*, 686 F.3d at 215 (concluding the scope of the patent does not allow any antitrust analysis).

103. *See* United States v. Singer Mfg. Co., 374 U.S. 174, 196 (1963) (establishing the main objective of an agreement cannot be to enforce broad market exclusion).

A. The General Antitrust Analysis of Rule of Reason Is the Best Analysis to Apply to Reverse Payment Agreements Because It Properly Balances the Rights of the Patent Holder with Adequate Antitrust Scrutiny.

The purpose of antitrust analysis in a patent claim is to ensure that the patent is not used in transactions between competitors to eliminate competition.[104] The patent antitrust claim in *In re K-Dur* requires inquiry into the pharmaceutical industry because the actions of Schering, Upsher, and ESI must be evaluated for their pro-competitive and anticompetitive effects on the market.[105] The rule of reason is the best analysis to evaluate the generic drug market because it incorporates many factors that holistically provide a reasonable conclusion about the pro-competitive and anticompetitive effects of reverse payment agreements.[106] Under the rule of reason, the reverse payment agreement in *In re K-Dur* creates an anticompetitive effect of eliminating competition while providing minimal pro-competitive benefits such as resolving patent infringement suits, thereby violating the Sherman Act.[107]

1. The Rule of Reason is the Best Option Because It Balances Antitrust Law with Patent Law.

The rule of reason is applicable for reverse payment agreements because complexities of the pharmaceutical market require the court's full inquiry in its antitrust analysis.[108] The settlement parties have legal rights that the court must uphold under patent law and the Hatch-Waxman Act while ensuring competition is not hindered in the market.[109] On the side most favorable to purchasers of drugs, the per se illegal analysis completely bars reverse payment agreements regardless of their positive effects.[110] On the side most favorable to drug manufacturers, the scope of the patent analysis

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104. *See id.* at 190 (applying the rule of reason when the court evaluated the sewing machine market and the course of dealings to conclude the patent license was an unreasonable restraint).

105. *See id*. (focusing on the competitors' agreement to pool their patents and enforce each others' in a concerted effort to restrain trade).

106. *See id.* (evaluating the number of competitors and the market share before and after the agreement).

107. *See In re K-Dur*, 686 F.3d at 218 (asserting there were few pro-competitive reasons for a reverse payment agreement).

108. *See id.* at 208 (explaining reverse payment agreements are only found in settlements under the Hatch-Waxman Act).

109. *See id.* at 217-18 (articulating the balance between innovation and public interest that courts must evaluate).

110. *See* Arizona v. Maricopa Cnty. Med. Soc'y, 457 U.S. 332, 344 (1982) (explaining that per se illegal distinctions are applied in general application for business certainty).

neglects the effect on the market.[111] In order to provide proper antitrust patent scrutiny, all factors must be reviewed to balance all of the parties' interests.[112]

The rule of reason analysis is better than the scope of the patent analysis because the rule of reason does not favor patent law over antitrust, but creates a balance between the laws.[113] Specifically, the rule of reason incorporates the scope of the patent in question as one factor that should be considered together with other factors.[114] The court must be allowed to look beyond the scope of the patent to evaluate whether the reverse payment agreements harm the generic drug industry or help make it more efficient.[115] Patent law is best balanced with antitrust law because while a patent holder may exclude competitors, it may not pool its resources or competitors to completely eliminate competitors from the market.[116]

In addition, the rule of reason is better than a per se designation because there is no consensus in the pharmaceutical industry that the anticompetitive effects of reverse payment agreements on the market outweigh the pro-competitive effects.[117] The rule of reason will uphold reverse payment agreements that work as a benefit to the market, while rejecting those that are anticompetitive.[118] This is a more balanced option than per se designation, which completely bars all reverse payment agreements.[119] Because Congress and others have reviewed reverse payment agreements and have not found them to be anticompetitive, the

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111. *See* Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003) (restricting the district court's antitrust analysis to exclusions that are beyond the patent's exclusionary effect).

112. *See Maricopa Cnty. Med. Soc'y*, 457 U.S. at 343 (articulating that the rule of reason requires the fact finder to evaluate all of the circumstances regarding a practice).

113. *See In re K-Dur*, 686 F.3d at 217 (arguing that rule of reason analysis strongly supports the line Congress drew between patent law and antitrust law).

114. *See* Bd. of Trade of Chi.v. United States,, 246 U.S. 231, 238 (1918) (including the relevant business, the effect, and the nature of the restraint in the court's rule of reason analysis).

115. *See* Broad. Music, Inc. v. Columbia Broad. Sys., Inc., 441 U.S. 1, 24 (1979) (maintaining that the license agreement receives more deference under the rule of reason because the rule of reason balanced copyright law with antitrust law).

116. *See* United States v. Singer Mfg. Co., 374 U.S. 174, 197 (1963) (explaining there are strict limits on concerted actions between patent holders to control the market).

117. *See Broad. Music*, 441 U.S. at 16 (observing a lack of universal view that blanket licensing was price-fixing).

118. *See id.* at 15 (explaining that per se designation does not provide any flexibility in inquiry).

119. *See id.* at 11 (concluding the practice should not be outlawed as a per se restraint regardless of the intensive antitrust scrutiny shown to the practice).

court must refrain from applying per se designations and instead use the rule of reason.[120]

2. Under the Rule of Reason, the Reverse Payment Agreement in In re K-Dur *Is a Violation of the Sherman Act Because It Supports More Anticompetitive than Pro-competitive Effects on the Market.*

Under the full rule of reason, the reverse payment agreement in *In re K-Dur* is a violation of the Sherman Act because Schering intended to eliminate market competition.[121] To determine whether the questioned practice is an unreasonable restraint of trade, various factors must be evaluated, including the relevant market, the scope of the patent, the parties' intentions, and the practical effect the practice has on the market.[122]

The relevant market is the generic controlled release potassium chloride market used for potassium deficiencies because the patent in question was the main consideration for the reverse payment agreement.[123] Under the context of the generic pharmaceutical industry, there are incentives for the pioneer drug company to maintain its monopoly and for the generic drug companies to delay entering the market.[124] The reverse payment agreement allowed Schering to maintain its monopoly on controlled release formulas and for Upsher and ESI to receive compensation for the profits they forfeited by delaying the market entry of their controlled release formulas.[125]

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120. *See id.* at 24 (concluding the background of the practice required further inquiry than per se designation would allow).

121. *See Singer*, 374 U.S. at 196 (concluding the parties' intention to eliminate the market is based on what they did rather than the labels applied); *In re* K-Dur Antitrust Litigation, 686 F.3d 197, 218 (3d Cir. 2012) (finding that the intent for the reverse payment was to delay generic market entry to maintain a monopoly).

122. *See* Bd. of Trade, of Chi. v. United States, 246 U.S. 231, 239-40 (1918) (observing the scope of the rule in question along with the effect and nature of the rule).

123. *Compare In re K-Dur*, 686 F.3d at 205 (rejecting the argument that the sixty million dollar payment to Upsher was for the drug Niacor, and thus narrowed the market to controlled release potassium chloride tablets), *with* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1070-71 (11th Cir. 2005) (concluding the sixty million dollar payment to Upsher was indeed a royalty for Niacor, and thus precluded the generic drug from hitting the market).

124. *See In re K-Dur*, 686 F.3d at 208, 218 (explaining a generic manufacturer takes over ninety percent of the patent holder's unit sales after the first year of market entry and concluding a reverse payment is prima facie evidence of an unreasonable restraint of trade because a reasonable generic manufacturer would not otherwise delay).

125. *See id.* at 218 (explaining a common sense application of the facts shows Schering paid Upsher and ESI to refrain from entering the market, which is an unreasonable restraint to trade).

The Court may look at the course of dealings between the parties to determine the true intent of the parties.[126] In the early proceedings, Upsher and ESI strongly defended their generic drugs as non-infringing and Upsher testified that the patent infringement claim was made in bad faith.[127] The Court could use this as evidence that Schering was in fear of losing its patent and therefore created the reverse settlement agreements in order to keep its patent.[128] However, Schering might argue that it simply wanted to settle to free up money and resources to return to creating drugs.[129] In the case at bar, Schering had more to lose if it lost the patent infringement case than if it settled because if it lost, Schering would have to split the profits, which were eight-times the amount paid in the settlement.[130] Thus, its intent was to uphold the patent and its profits through the reverse payment agreement.[131]

The Court will also evaluate whether the actions could reasonably eliminate competition.[132] A concerted action to restrain competitors is a violation of the Sherman Act.[133] Schering signed reverse payment agreements with two of its competitors in the controlled release potassium chloride market.[134]

Whether Schering paid off all the competitors is unknown; however, the reverse payment agreements give Schering illegal control of the generic market because subsequent generic market entry is cost-prohibitive for

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126. *See Singer*, 374 U.S. at 189-90 (stating the patent holder's conversations prior to the agreement were evidence of an illegal intent to eliminate competition).

127. *See In re K-Dur*, 686 F.3d at 205 (describing Upsher's contention that their coating contained a different composition than the patented drug, and ESI's argument that their coating was multilayered and therefore unlike the single layer of the patented drug).

128. *See id.* at 205 (explaining the Upsher agreement came just hours before cross motions for summary judgment).

129 *See* Valley Drug Co. v. Geneva Pharm., 344 F.3d 1294, 1308 (11th Cir. 2003) (asserting that restricting settlements will increase the cost of patent enforcement and harm innovation).

130. *See In re* Schering-Plough Corp., 136 F.T.C. 956, 980 (2003), *vacated*, Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005) (noting Schering's internal analysis revealed annual sales were $190 million prior to the settlement).

131. *See In re K-Dur*, 686 F.3d at 218 (concluding the reverse payment was quid-pro quo for delaying market entry).

132. *See Singer*, 374 U.S. at 190 (concluding the party's actions had the potential to eliminate foreign competitors); Broad. Music Inc. v. Columbia Broad. Sys., Inc., 441 U.S. 1, 29 (1979) (concluding available alternatives did not eliminate competition).

133. *See Singer*, 374 U.S. at 195 (concluding the competitors market was reduced by the illegal agreement).

134. *See In re K-Dur*, 686 F.3d at 205-06 (explaining that Upsher filed its ANDA just months prior to ESI filing its ANDA).

subsequent paragraph IV filers.[135] If a subsequent filer is successful in invalidating Schering's patent, there will be four competitors in the market and less revenue for the generic company who was not a party to the settlement.[136] The decreased revenue reduces the incentive to challenge the patent because the generic manufacturer will be less likely to recoup its market entry costs.[137] Moreover, if Upsher and ESI have a patent on their versions of controlled release, the third generic company will have to fight and win three patent infringement claims before it could share in a saturated market.[138] Patent infringement suits further increase the costs to enter the market and make the generic pharmaceutical market cost-prohibitive.[139] By making generic market entry cost-prohibitive, Schering's reverse payment agreements eliminate the competition in the generic market for controlled release potassium chloride tablets and grant Schering full control of the market.[140]

3. Pro-competitive Defenses for the Reverse Payment Agreement in In re K-Dur *Provide Minimal Benefits.*

Schering, Upsher, and ESI will need to rebut the plaintiff's claim that the payments were for market entry delay by providing sufficiently pro-competitive reasons for their agreement or a showing that the money was not for the delay.[141] The defendants argued that the payment was a

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135. *See* United States v. United States Gypsum Co., 333 U.S. 364, 384 (1948) (finding the license agreement illegally eliminated competition by restraining production of gypsum products, making it difficult for competitors to remain in business); *see also* Hemphill, *supra* note 21, at 1583 (referring to the 180-day exclusion period as an incentive for the generics to overcome the costs of filing).

136. *See In Re Schering-Plough*, 136 F.T.C. at 980 (stating Schering's internal analysis calculated that total K-Dur revenue would fall to seventy million dollars in 2001); Hemphill, *supra* note 21, at 1580-1581 (explaining that profits are reduced and spread out across manufacturers when there are more than two competitors).

137. *See In re K-Dur*, 686 F.3d at 218 (concluding the generic manufacturer receives the reverse payment to help recoup its cost for manufacturing); Hemphill, *supra* note 21, at 1581 (explaining that fewer challengers reduces the rate of the patent being found invalid and increases the incentive to settle and pay for delay).

138. *See In re K-Dur*, 686 F.3d at 217 (arguing that reverse payment agreements discourage patent challenges which is contrary to the purpose of the Hatch-Waxman Act); Hemphill, *supra* note 21, at 1582 (noting there are a limited number of firms capable of challenging a pioneer company's patent).

139. *See* United States v. Singer Mfg. Co., 374 U.S. 174, 195 (1963) (concluding the concerted effort to attack infringers of the combined patents was an unreasonable restraint of trade).

140. *See U.S. Gypsum Co.*, 333 U.S. at 382 (holding the minimum price setting in the license agreement restricted competition because the market was controlled and not free).

141. *See In re K-Dur*, 686 F.3d at 218 (finding a reverse payment agreement a prima

licensing fee for a different drug and is in accordance with their patent law rights.[142] While the agreement appears to work as a licensing agreement to sell other drugs, a fact finder could logically conclude that the main purpose of the sixty million dollar payment was to delay generic marketing of K-Dur.[143] The license agreement included one other generic drug, Niacor, which was subsequently abandoned.[144] Therefore, a reasonable fact finder could conclude that the main purpose of the settlement would pertain to the K-Dur patent and not to license Niacor.[145]

The defendants could also argue that their main purpose was to end the litigation in accordance with public policy.[146] This argument is weakened because the settlement came after costly discovery had already concluded.[147] The court could have found that Upsher did not infringe on the patent because the generic drug had a different coating than the patent.[148] Further, Upsher and ESI asserted that the chemical composition of their drugs differed from Schering's, which would mean a non-infringement of the patent if properly argued.[149]

The agreed upon delayed market entry dates also provide evidence of excluding other competitors and giving Schering four more years as a monopoly.[150] The plaintiff could argue that Upsher and ESI would not

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facie case of unreasonable restraint without offsetting considerations).

142. *See id.* at 206 (explaining the major dispute of the parties was the purpose of the payment).

143. *See id.* (explaining the drug companies stopped selling the licensed drug after the settlement was ratified by Schering's board of directors). *But see* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1070 (11th Cir. 2005) (rejecting the FTC's expert's determination that Niacor was not worth sixty million dollars).

144. *See Schering-Plough*, 402 F.3d at 1070-71 (concluding the main consideration for the agreement was to obtain a license for Niacor).

145. *See In re K-Dur*, 686 F.3d at 205-06 (describing why Schering sued Upsher and ESI for patent infringement).

146. *See In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 202 (2d Cir. 2005) (stating a policy of courts encouraging settlements).

147. *See In re K-Dur*, 686 F.3d at 205 (explaining the settlement came prior to the court ruling on summary judgment).

148. *See id.* (quoting Upsher calling the infringement claim baseless and not made in good faith because the products had different compositions).

149. *See id.* (describing that Upsher's release coating was a different chemical composition, and ESI's drug used a multilayered coating while Schering's drug had one layer of coating and a different viscosity). *See generally* Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 813 (D.C. Cir. 2001) (assuming a generic competitor would not reasonably delay marketing its drug).

150. *See In re K-Dur*, 686 F.3d at 217 (stating the purpose of the Hatch-Waxman Act was for Congress to provide low cost medicine to the consumer); Kelly, *supra* note 1, at 426 (stating the entry of generic drugs reduces the price of medicine, saving the

agree to delay market entry if no payment were provided.[151] Further, that the varying amounts were provided to ESI prior to the agreed upon marketing date, but contingent upon FDA-approval, provides evidence that the main concern of Schering was to maintain its K-Dur monopoly.[152] Therefore, a reasonable fact finder could conclude that the purpose of the agreement was to exclude competition in violation of the Sherman Act.[153]

B. Per Se Illegal Analysis Is Not the Right Analysis for Reverse Payment Agreements Because Per Se Designation Will Preemptively Negate All Reverse Payment Agreements Without Providing Sufficient Inquiry Under the Sherman Act.

Per se illegal analyses are broad-sweeping and, if applied, will automatically bar reverse payment agreements in all cases.[154] After reviewing the practice, surrounding industry, congressional response, and the historical impact, a general understanding of the practice is established to determine whether all reverse payment agreements are categorically illegal.[155] The per se illegal analysis should not apply to reverse payment agreements because the balance between patent law and antitrust law requires more inquiry to properly ascertain the competitive effects.[156]

1. Arguments Against Applying the Per Se Illegal Analysis

To determine whether per se illegal designation should apply to all reverse payment agreements and not just the one in *In re K-Dur*, the pros and cons of multiple reverse payment agreement cases must be

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public eight to ten billion dollars in drug costs in 1994).

151. *See Andrx Pharms.*, 256 F.3d at 813-14 (comparing the actions of the generic competitor to those of an objectively reasonable competitor).

152. *See In re K-Dur*, 686 F.3d at 206 (ESI's "licensing" varied from ten million if the ANDA was approved, to six-hundred and twenty-five thousand dollars if not approved by the FDA).

153. *See* United States v. Singer Mfg. Co., 374 U.S. 174, 196 (1963) (holding the "common" purpose of suppressing competition was a violation of Sherman Act).

154. *See* Arizona v. Maricopa Cnty. Med. Soc'y, 457 U.S. 332, 344 (1982) (explaining that per se illegal designation concludes further inquiry under the rule of reason once a horizontal price-fixing agreement is found and negates the positive benefits).

155. *See* Broad. Music, Inc. v. Columbia Broad. Sys., Inc., 441 U.S. 1, 10 (1979) (asserting that the conditions in copyright and antitrust law must both be evaluated in the antitrust analysis to account for both).

156. *See id.* at 20 (holding per se analysis did not apply because the license had pro-competitive benefits within copyright law that were sufficient to require a deeper analysis).

evaluated.[157] Because the antitrust analysis must balance patent interests with antitrust interests and Congress has implicitly allowed reverse payment agreements, the per se illegal analysis should not apply.[158]

i. The Underlying Patents of Reverse Payment Agreements Must Be Evaluated Because Patents Provide a Legal Monopoly.

Under the antitrust analysis of the court, the reverse payment agreements of *In re K-Dur* are not per se illegal because the agreements are based on a patent that provides a legal monopoly in the pharmaceutical industry.[159] Schering received a patent for K-Dur that gives it the right to exclude others from using it.[160] Until the patent expires or is found invalid, Schering will continue to have the right of exclusion, and the court will respect that right.[161] However, a per se illegal analysis will preclude further inquiry about the manner in which Schering used its patent within that monopoly.[162] A per se illegal analysis completely negates patent law because it only looks at the agreement as it relates to antitrust and fails to place the agreement in the context of the patent owner's rights.[163] The Court must balance patent and antitrust law by not applying a per se illegal analysis but by applying the rule of reason.[164]

ii. Reverse Payment Agreements Possess Pro-competitive Benefits.

The Court will also look for pro-competitive benefits for reverse payment agreements to determine whether they are facial restraints to

157. *See id.* at 8, 14, 20 (evaluating the entire copyright industry, congressional review, the pro-competitive benefits, and whether the license was price-fixing to determine whether the practice generally is anti-competitive).

158. *See id.* at 15, 20 (concluding the license improved efficiency, was used by Congress, and there were alternatives in the market).

159. *See id.* at 19 (arguing that licensing agreements based on copyright laws provide rights of restriction to the copyright holder that are not per se illegal).

160. *See* 35 U.S.C. § 271 (2006 & Supp. 2010) (defining infringement as using or selling any patented material without authorization).

161. *See* United States v. Singer Mfg. Co., 374 U.S. 174, 190 (1963) (explaining antitrust does not evaluate the patent holders right to exclude, but rather the agreements to exclude).

162. *See id.* at 196 (using the rule of reason to analyze the limits of the patent monopoly).

163. *See In re* K-Dur Antitrust Litig., 686 F.3d 197, 216 (3d Cir. 2012) (recognizing the analysis must be sensitive to the regulated industry of patents).

164. *See* United States v. U.S. Gypsum Co., 333 U.S. 364, 390-91 (1948) (concluding that using patent licensing to control price and output was beyond the rights of the patent); *see also Broad. Music*, 441 U.S. at 14-16 (finding a practice is not per se illegal if it benefits the particular industry under the circumstance).

trade.[165] A redeeming quality of reverse payment agreements is their ability to operate as licensing agreements.[166] Typically, a patent holder issues a license to a possible infringer to grant the infringer access to a particular market in return for payment.[167] Licensing allows Schering to open the K-Dur patent rights to others for a fee that is then used by Schering to recoup its initial investment in developing K-Dur.[168] Although Schering delayed granting the license to Upsher and ESI, further inquiry is needed to determine the harm on the market from this restriction.[169] It would be premature analysis to find reverse payment settlement agreements that are used as a licensing tool to be per se illegal because it would harm the purpose of patent law.[170]

Another redeeming quality of reverse payment settlements is that they provide efficient resolution of patent infringement litigation, and courts encourage settlements.[171] Patent infringement litigation is expensive, and a settlement can bring down the cost of enforcement.[172] The Schering-Upsher patent infringement litigation in *In re K-Dur* lasted for two years before the parties agreed on a settlement.[173] A court could reasonably

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165. *See Broad. Music*, 441 U.S. at 23 (explaining that the court looks for a hindrance to competition in the market as a result of the agreement).

166. *See* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1067-68 (11th Cir. 2005) (explaining the Schering's agreement with Upsher was a license under the patent); Valley Drug Co. v. Geneva Pharms., 344 F.3d 1294, 1304 (11th Cir. 2003) (analogizing reverse payment agreements with licensing).

167. *See Valley Drug*, 344 F.3d at 1304 (explaining the main purpose of the patent is to regulate exclusion).

168. *See id.* at 1304 (explaining the incentive for patents is to induce investment in innovation).

169. *See In re* K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012) (concluding a payment in conjunction with a delay was prima facie evidence of an unreasonable restraint that could be rebutted by evidence showing otherwise).

170. *See Valley Drug*, 344 F.3d at 1304 (rejecting per se violation of the Sherman Act because the patent gave a legal monopoly).

171. *See Schering-Plough*, 402 F.3d at 1072-73 (arguing public policy encourages settlements of patent litigation).

172. *See Valley Drug*, 344 F.3d at 1308 (arguing that restricting patent infringement settlement will increase the cost of patent enforcement, and discourage innovation). *See generally* Eli Lilly Co. v. Zenith Goldline Pharms., Inc., 264 F. Supp. 2d 753, 784 (S.D. Ind. 2003) (concluding attorneys fees for prevailing party in patent drug infringement case were approximately $1.5 million); Christopher Ryan Lanks, Note, In re Seagate*: Effects and Future Development of Willful Patent Infringement*, 111 W. VA. L. REV. 607, 635 (2009) (explaining prior to *In re Seagate* the costs of an average patent litigation case are between one and four million).

173. *See In re K-Dur*, 686 F.3d at 205-06 (explaining that even after litigating for two years, Schering and Upsher took two and a half months to work through the settlement).

assume that Schering wanted to end the precedent litigation and continue to remain out of court when Schering and ESI used court-supervised mediation to handle their patent infringement claim.[174] There would need to be more deferential review than a per se illegal standard to determine an unreasonable restraint to trade because settlements are a pro-competitive benefit.[175]

iii. Congressional Review Did Not Find Reverse Payment Agreements to Be Monopolistic or Harmful to Competition.

A per se illegal designation has also been found inappropriate when Congress has reviewed the action and upheld it.[176] Congress reviewed and heard testimony regarding reverse payment agreements in 2003 and did not find the practice harmful enough to amend the statute to outlaw reverse payment agreements under the Hatch-Waxman Act.[177] Instead of banning reverse payment agreements, Congress recognized some beneficial qualities to the practice, and left the court to continue case-by-case review.[178] Accordingly, if Congress implicitly endorses the agreement because no harm is found, the court will give more deference to the congressional findings and not apply a per se illegal analysis.[179]

2. Arguments for Applying a Per Se Illegal Standard That Are Not Sufficient

While the reverse payment agreement in *In re K-Dur* may be beneficial, a per se illegal analysis may apply if the court can determine a clear elimination of alternatives in the market.[180] In this instance and others, a

174. *See id.* at 207 (describing the parties argued that they felt judicial pressure to settle).

175. *See Schering-Plough*, 402 F.3d at 1073 (arguing the restraint created by the settlement cannot "extinguish competition without creating efficiency").

176. *See* Broad. Music, Inc. v. Columbia Broad. Sys., Inc., 441 U.S. 1, 15-16 (1979) (deferring to Congressional findings that provided positive findings for the licensing action).

177. *See* Judiciary, *supra* note 30, at 5 (statement of Timothy J. Muris, Chairman, Federal Trade Commission) (describing fourteen settlement agreements that had the potential to create a bottleneck in the generic drug market); Kelly, *supra* note 1, at 442-43 (explaining the amended Hatch-Waxman Act incorporated a provision that requires filing of paragraph IV settlement agreements with both the FTC and DOJ).

178. *See In re K-Dur*, 686 F.3d at 217 (holding the rule of reason balances the competing objectives of antitrust and patent law that Congress was attempting to maintain when creating the Hatch-Waxman Act).

179. *See Broad. Music*, 441 U.S. at 16 (deferring to Congress' assessment of the economic benefit of blanket licensing in copyright law).

180. *See id.* at 24, n.40 (concluding there was no monopoly if alternative forms of licensing were available).

per se illegal analysis is not applicable because there is no clear restraint on the market, and further inquiry is needed to determine the restraint.[181]

i. Clear Lack of Alternatives: Reverse Payment Agreements That Manipulate the 180-Day Exclusion Period May Be Held Per Se Illegal

Under this circumstance, the only clear method of eliminating competition is by retaining the 180-day exclusion period.[182] The 180-day exclusivity right is only given to the first generic drug company who files a paragraph IV certification for a generic drug and is lost if the first generic filer does not use it.[183] In this instance, Upsher would be the first paragraph IV filer and have the right to the 180-day exclusion period.[184] A subsequent paragraph IV filer who successfully invalidates the patent will be unable to go to market unless Upsher abandons its right to the 180-day exclusion period.[185] Retaining the right would wrongly bar all alternative generic manufacturers from entering the market and create an argument for per se illegal analysis.[186]

However, in this instance, Upsher did not retain the 180-day exclusion period, and other generic manufacturers could possibly market their drug upon approval from the FDA.[187] The Court would need to do further inquiry on the effect of the reverse payment agreement to determine the size of the market and whether Schering illegally eliminated the

181. *See id.* at 20 (concluding the license agreement did not plainly show an unreasonable restraint).

182. *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1340 (Fed. Cir. 2008) (asserting that a crucial factor in finding no antitrust claim was that the 180-day exclusion right was not retained, thus allowing other generic manufacturers to challenge the patent in that time).

183. *See id.* at 1328 (explaining the 180-day exclusion period is triggered when the first ANDA filer begins to market the drug or when a final court order finds the patent is invalid). See *generally* Kelly, *supra* note 1, at 16 (explaining that the FDA must wait until the 180-day exclusivity period to approve a subsequent ANDA).

184. *See In re* K-Dur Antitrust Litig., 686 F.3d 197, 205 (3d Cir. 2012) (noting that Upsher filed in August 1995 whereas ESI filed in December 1995).

185. *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d at 1335 (finding anticompetitive effects when the first ANDA filer agrees not to market and not to relinquish the 180-day exclusion period).

186. *See Broad. Music*, 441 U.S. at 24 (weighing the presence of available alternatives as a factor that can negate per se illegality).

187. *See In re K-Dur*, 686 F.3d at 211 (stating the Schering-Upsher agreement did not involve bottlenecking by manipulating the 180-day exclusivity period).

competition.[188] Therefore, per se illegal analysis is not appropriate for reverse payment agreements because all reverse payment agreements do not clearly eliminate competition by manipulating the 180-day exclusion period.[189]

ii. Reverse Payment Agreements Are Similar to Horizontal Price-Fixing, but Too Attenuated.

Reverse payment agreements should not be analogized to horizontal price-fixing and deemed per se illegal for controlling pricing.[190] The K-Dur reverse payment agreement ensured that Schering's drug remained the only one on the market, and thus would have complete control of the price.[191] Schering's patent does not grant the right to control the price of K-Dur but merely the right to exclude others from selling generic versions of it.[192] Although Schering eliminated two competitors from the market, further inquiry is needed to determine whether all competitors were eliminated so as to give Schering control of the K-Dur market price.[193] Schering's actions are not a literal example of price-fixing, and therefore require further inquiry into the K-Dur market, which is not applicable to a per se illegal analysis.[194]

iii. Historical Negative Impact on the Market Needs Further Review.

Lastly, reverse payment agreements fail to clearly establish an unreasonable restraint to trade.[195] The history of reverse payment

188. *See Broad. Music*, 441 U.S. at 20 (explaining that after further review of the blanket license, the Court found the blanket license arose out of circumstances in the copyright market and is beneficial in that context).

189. *See id.* at 23 (concluding that not all agreements between competitors that effect price are per se violations).

190. *See* United States v. U.S. Gypsum Co., 333 U.S. 364, 398-99, 400 (1948) (holding that the patent holder's license provision that required a minimum price for gypsum products was price-fixing, and per se illegal).

191. *See In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 907 (6th Cir. 2003) (holding reverse payment agreements as a horizontal agreement to fix the price because the agreement eliminated the only competition in the market).

192. *See U.S. Gypsum*, 333 U.S. at 400 (explaining that patent holders can use their patent to exclude at varying degrees, but cannot use their patents to monopolize an industry through price control).

193. *See Broad. Music*, 441 U.S. at 23-24 (holding per se illegal analysis was not applicable because buyers had other price options).

194. *See U.S. Gypsum*, 333 U.S. at 400 (holding that placing a minimum price in the licensing agreement between all the competitors was a clear example of price-fixing).

195. *See* Arizona v. Maricopa Cnty. Med. Soc'y, 457 U.S. 332, 344, (1982) (explaining that a history of negative experience with the activity may warrant classification as a per se violation).

agreements, similar to the one in *In re K-Dur*, establishes that an overwhelming number of reverse payment agreements unreasonably restrain trade.[196] Precedent shows that reverse payment agreements that manipulate the 180-day exclusion period typically restrain trade, but these are not found in every reverse payment agreement such as the case at bar.[197]

In conclusion, reverse payment agreements that do not manipulate the 180-day exclusion period are not facial restraints to competition because there is no clear restraint on trade.[198] Without a clear restraint on trade, the rule of reason should be used to determine whether the pro-competitive benefits outweigh the anticompetitive effects and to determine if there are alternatives in the market.[199] Because reverse payment agreements are not facial restraints to competition and Congress has allowed them to remain, the per se illegal analysis for antitrust does not apply.[200]

C. The Scope of the Patent Standard is the Least Appropriate Analysis for Reverse Payment Antitrust Claims Because It Preemptively Favors Reverse Payment Agreements Without Providing a Sufficient Inquiry Under the Sherman Act.

When the Eleventh Circuit created the scope of the patent analysis, it incorrectly prioritized patent law concerns over the general aims of antitrust.[201] The Hatch-Waxman Act was proposed as a compromise that

196. *See id.* (explaining that repeatedly inquiring into the market effects of a frequent business practice is a significant endeavor that courts attempt to reduce by applying per se rules).

197. *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1339 (Fed. Cir. 2008) (concluding that refusing to relinquish the 180-day exclusivity right while agreeing to delay marketing may be found anticompetitive); Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 811 (D.C. Cir. 2001) (holding that the 180-day exclusion period could reasonably be viewed as an attempt to maintain a monopoly).

198. *See Broad. Music*, 441 U.S. at 24 (holding that price setting of licensing fees required further review than per se designation required); Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1304 (2003) (arguing that patent law creates an exclusionary right and agreements with patents should be analyzed further within the context of the exclusionary right).

199. *See In re* K-Dur Antitrust Litig., 686 F.3d 197, 217 (3d Cir. 2012) (asserting that applying the rule of reason does not discourage settlements which are a pro-competitive benefit); *see also* Kelly, *supra* note 1, at 431 (describing a reverse payment agreement that did not allow the generic drug company to market its drug until the patent expired, thus providing a patent monopoly extension of at least 180-days).

200. *See Broad. Music*, 441 U.S. at 24 (concluding the unique factors in the copyright industry preclude the blanket license from appearing as a facial restraint to trade).

201. *See In re K-Dur*, 686 F.3d at 214 (taking issue with the presumption of patent validity in using the scope of the patent analysis without evaluating the other factors in

would balance the patent rights of pioneer drug companies with the need for generic drug competition.[202] Congress wanted to allow generic companies to file a paragraph IV certificate to legally enter the market and challenge weak patents.[203] The scope of the patent harms this balance by asserting patent law interests over any antitrust claim.[204]

1. Scope of the Patent Analysis Favors Reverse Payment Agreements Regardless of Patent Validity.

When Schering filed an infringement suit, it asserted its patent was valid, but this is a legal conclusion that can only be legally presumed in non-infringement claims upon successful defense of the patent validity.[205] In the course of determining the scope of the patent, the Court should not legally conclude the patent is valid.[206] The validity presumption rejects the purpose of the patent infringement case in determining whether the pioneer drug company's rights have been infringed.[207] Considering that reports have found generic drug companies successfully challenge patent infringement claims in seventy-three percent of Hatch-Waxman claims, a presumption of validity does not correspond with reality.[208] Allowing

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the rule of reason).

202. *See id.* at 217 (explaining that Congress balanced patent rights and the public need for drugs with the Hatch-Waxman Act that the rule of reason respects). *See generally* Avery, *supra* note 3, at 175-76 (describing the two policies of the Act as encouraging research by pioneer drug companies, and allowing generic drug companies to get FDA approval in a cheaper manner).

203. *See* 35 U.S.C. § 355(j)(2)(A)(vii)(IV) (2010); *see also* Kelly *supra* note 1, at 9 (stating that the Hatch-Waxman Act revised the Patent Act so that filing an ANDA under subsection IV was a technical act of patent infringement, thus creating an early and beneficial resolution as to patent validity).

204. *See* Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003) (citing Standard Oil Co., Ind., v. United States, 51 S. Ct. 421, 425-26 (1931)) (confining antitrust scrutiny to provisions beyond the exclusionary effect of the patent).

205. *See In re K-Dur*, 686 F.3d at 205-06 (finding that filing a patent infringement suit against the generic drug companies gave Schering a 30-month automatic stay against Upsher's ANDA approval); Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983) (holding that patent validity is only a procedural device and not substantive law); *see also* Ashcroft v. Paper Mate Mfg. Co., 434 F.2d 910, 914 (9th Cir. 1970) (concluding the patent validity is a presumption that is merely an aid to inquiry and does not automatically conclude thought and analysis).

206. *See In re K-Dur*, 686 F.3d at 214 (arguing presumption that a patent holder has the right to exclude is misguided where the underlying suit concerns patent infringement).

207. *See id.* (explaining the purpose of the patent infringement case is to argue validity of the patent).

208. *See id.* (finding issue with presuming a patent is valid because the presumption asserts that the patent holder would have won the patent infringement suit). *See*

reverse payment agreements through the scope of the patent analysis allows the pioneer drug company to assert rights that it no longer has.[209]

Furthermore, the scope of the patent analysis circumvents patent law because the reverse payment agreement upholds patent validity where the court has determined none exists.[210] In *Valley Drug*, the Eleventh Circuit effectively overruled the district court's holding of an invalid patent when it applied the scope of the patent analysis.[211] The district court applied patent law in the patent infringement claim to determine that the patent was invalid, thus denying the pioneer company's right to exclude.[212] The settling parties agreed to uphold the patent regardless of the court's ruling.[213] By allowing the reverse payment agreement based on its exclusionary power, the Eleventh Circuit created a new patent right that allowed a patent to be made valid through mutual agreement between parties and not by patent law.[214]

Patent validity agreements are beyond the scope of the patent and do not fulfill the purpose of patent law.[215] Patent law was created to grant an exclusionary right to a patent holder who met the requirements of patentability, novelty, and non-obviousness.[216] Patent litigation is costly, but provides a competitor and the public with important information as to who holds the right to exclude competition through a valid patent.[217] Allowing parties to create a contractual patent for a weak or invalid patent

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generally Kelly, *supra* note 1, at 16 (explaining the FTC study of drug companies that took place between 1992 and 2000).

209. *See In re K-Dur*, 686 F.3d. at 215 (arguing a reverse settlement agreement allows the patent holder of a weak patent to buy its way out of competition).

210. *See* Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1305 (11th Cir. 2003) (concluding the reverse payment agreement was not based on fraud because the patent was valid at the time of the agreement).

211. *See id*. at 1308-11 (disregarding the lower courts holding of patent invalidity, and applying valid patent rights to the reverse payment agreement).

212. *See id.* at 1305 (concluding the reverse payment agreement was a legal agreement based on the patent rights because it was made prior to the patent being held invalid).

213. *See id*. at 1300 (stating that although a provision terminated the agreement upon patent invalidation, the settling parties did not terminate the agreement until the FTC began investigating the arrangement).

214. *See In re K-Dur*, 686 F.3d at 215 (arguing a pioneer patent holder can buy its way out of competition and invalidation).

215. *See* Pope Mfg. Co. v. Gormully, 144 U.S. 224, 234 (1892) (explaining the public interest in not allowing worthless patents to hinder competition).

216. *See* 35 U.S.C. §§ 101, 102, 103, 112 (2006 & Supp. 2010).

217. *See* Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 330 (1945) (asserting that courts should still discuss the validity of a patent, regardless of whether the patent infringes, because validity has the greater public importance).

does not properly reward the inventor for her invention, but improperly excludes others within the confines of the Hatch-Waxman Act.[218] Non-party generic companies will have to re-litigate the validity of a previously deemed invalid patent, only to receive access to the market later.[219] During this time, the pioneer drug company has a contract creating a right to exclude.[220] This result is clearly beyond the scope of the patent because there is no valid patent and therefore no right to exclude.[221]

The scope of the patent analysis should not apply to reverse payment agreements because it improperly bases its analysis on a presumption of patent validity and goes beyond the scope of the patent by upholding the exclusionary effect of invalid patents.[222] The scope of the patent analysis is properly rejected because it circumvents patent law.[223]

2. The Scope of the Patent Analysis Is One Factor of Many That Is Required to Sufficiently Evaluate an Antitrust Claim.

The scope of the patent analysis is not applicable to antitrust reverse payment claims because it precludes further inquiry into the relevant market.[224] In *Schering-Plough Corp.*, the FTC brought an antitrust claim against the same parties as in *In re K-Dur*, but it came to a different conclusion under the same facts.[225] The difference was the result of the

218. *See* Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 101 (1993) (explaining that dismissing a judgment on a patent that was found invalid creates an unnecessary burden on competitors to re-litigate).

219. *See In re K-Dur*, 686 F.3d at 204 (explaining subsequent generic companies will be less likely to attempt to enter the market because the 180-day exclusivity period is the main incentive for generic companies and is only given to the first one to file a paragraph IV certification).

220. *See id.* at 205 (explaining that in the Schering-Upsher agreement, Upsher did not concede the validity or infringement of Schering's patent, but merely agreed to delay marketing).

221. *See id.* at 217 (arguing the strength of the patent will be based on the patent holder's ability to pay off competitors, which is contrary to the policy behind the Hatch-Waxman Act).

222. *See* United States v. Singer Mfg. Co., 374 U.S. 174, 196-97 (1963) (explaining the patent holder has narrow limitations in patent agreements).

223. *See In re K-Dur*, 686 F.3d at 218 (arguing that a patent holder is more likely to settle to retain its patent when the patent is weak or too broad).

224. *Compare id.* at 212 (holding the Schering-Upsher-ESI reverse payment agreement unreasonable under the rule of reason), *with* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005) (holding the Schering-Upsher-ESI reverse payment agreement reasonable under the scope of the patent).

225. *See Schering-Plough*, 402 F.3d at 1065 (rejecting the rule of reason and per se analysis because the court regarded the analyses as "ill suited for an antitrust analysis of patent cases").

Eleventh Circuit hinging its analysis on a presumption of the patent's validity.[226] Schering's patent validity is a minor factor in antitrust claims because general antitrust scrutiny does not centralize itself upon whether a patent is valid.[227] General antitrust scrutiny focuses on the contractual agreement to monopolize and how it affects the market, not whether the underlying legal monopoly was valid.[228] Regardless of whether Schering's patent is strong or weak, the antitrust analysis hinges on the concerted action between Schering, Upsher, and ESI to determine whether an antitrust violation has occurred.[229] The scope of the patent analysis fails to review the agreement and the effect on the market, thus failing to provide antitrust scrutiny to reverse payment agreements.[230]

The scope of the patent analysis is only one part of the antitrust analysis required because it fails to evaluate important factors such as the relevant market.[231] General antitrust scrutiny requires that factors related to the coated potassium tablet market be evaluated as a whole.[232] An evaluation of the scope of Schering's patent monopoly is helpful in determining the market that the court should be concerned with, but should not be the end of the analysis.[233] Understanding Schering's patent scope allows the court to focus on controlled release coated potassium chloride tablets and use the circumstances to determine how that market is restrained.[234] The scope of

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226. *See In re K-Dur*, 686 F.3d at 214 (asserting the scope of the patent analysis relies on an unrebuttable presumption of patent validity that only favors the patent holder and is not in accordance with antitrust analysis).

227. *See* United States v. U.S. Gypsum, 333 U.S. 364, 387 (1948) (concluding that finding the patent invalid is not needed to determine antitrust liability).

228. *See* Katzinger Co. v. Chi. Metallic Mfg. Co., 329 U.S. 394, 401 (1947) (concluding the contract was still illegal regardless of the validity of the patent).

229. *See* United States v. Singer Mfg. Co., 374 U.S. 174, 189 (1963) (explaining the antitrust issue does not involve a patent holder's right to exclude, but rather, whether the patent holder has the right to contractually exclude others).

230. *See In re K-Dur*, 686 F.3d at 218 (concluding the rule of reason applies because it will evaluate the actual effect on the market and not conclude the analysis based on the settling party's labeling).

231. *See* Ill. Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28, 33-34 (2006) (explaining the analysis for patent antitrust claims evaluates the concerted effort to exploit the patent monopoly and increase its effect on the market).

232. *See* Bd. of Trade of Chi. v. United States, 246 U.S. 231, 238 (1918) (reprimanding the district court judge for basing his conclusion on an opinion about the general activity of bidding for grain, without inquiring into the particular business surrounding the activity, thus placing it into context).

233. *See id.* at 239 (applying a three prong test that looked at the nature of the rule, the scope of the rule, and the effects of the rule in question).

234. *See In re K-Dur*, 686 F.3d at 204 (explaining that the patent covers controlled-release potassium chloride tablets).

the patent analysis fails to acknowledge one of the most important parts of antitrust principles: the actual effect on the market.[235]

IV. POLICY RECOMMENDATION

Although some reverse payment agreements may be found legal, as a policy consideration, they should be banned because they undermine the purpose of the Hatch-Waxman Act.[236] A major underlying purpose of the Hatch-Waxman Act is to reduce the generic manufacturer's cost of FDA approval so that competition can thrive.[237] Allowing reverse payment agreements negates this purpose because the generic manufacturers are no longer entering the market and competition is restrained.[238] Reverse payment agreements place the market at pre-Hatch-Waxman Act levels by allowing the pioneer manufacturers to maintain their monopolies on weak or narrow patents.[239] A monopoly in the pharmaceutical market where generic manufacturers are present, but not marketing, is contrary to the purpose of the Hatch-Waxman Act, and therefore, reverse payment agreements should be banned.[240]

Reverse payment agreements also negate the ultimate purpose of the Hatch-Waxman Act by restricting pharmaceutical drug access to the public.[241] Congress hoped to reduce pharmaceutical costs to the public by allowing generic drug entry that would create competition.[242] The increase in competition would force competitors to lower the drug price and the

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235. *Compare* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005) (concluding under the scope of the patent analysis that the payments from Schering to Upsher were to license a different patent as stated by the settling parties), *with In re K-Dur*, 686 F.3d at 218 (concluding that under the rule of reason,the payment was for delaying because no reasonable generic manufacturer would delay going to market were they not paid).

236. *See* Hemphill, *supra* note 21, at 1614 (stating Congress used the Act to balance innovation with competition).

237. *See* Kelly, *supra* note 1, at 420 (explaining that the Act resolved years of controversy over FDA approval requirements for generic pharmaceutical manufacturers).

238. *See In re K-Dur*, 686 F.3d at 217 (explaining Congress wanted to encourage generic manufacturers to challenge patented drugs).

239. *See id.* (asserting that the pioneer manufacturer is able to maintain its patent based on the strength of its wallet).

240. *See id.* (calling reverse payment agreements a form of "self- help" that was not conceived of by Congress when originally passing the Hatch-Waxman Act).

241. *See id.* (declaring that Congress sought to protect the public from high pharmaceutical costs).

242. *See* Kelly, *supra* note 1, at 426 (explaining the generic industry filled more than fifty-three percent of the 2004 prescriptions).

public would reap the benefits.[243] Allowing reverse payment agreements maintains the status quo in the market, and the public does not receive cheaper drugs.[244] The only ones who benefit in a reverse payment agreement are the manufacturers, while the reduced cost to the public is lost.[245]

In order to reconcile the competitive purpose of the Hatch-Waxman Act with reality, Congress should ban reverse payment agreements for their restraint on competition and the harm to the American people.[246]

V. CONCLUSION

When the United States Supreme Court considered the issue in a precedent sister case, it was able to state a single clear standard of analysis to balance the country's antitrust law with respect to reverse payment agreements under the Hatch-Waxman Act.[247] The Court upheld the rule of reason analysis, finding that the rule of reason is applicable to reverse payment agreements because the legal monopolies created by patent law and the Hatch-Waxman Act require further review of the facts.[248] This paper agrees that courts must fully examine the facts surrounding industry factors on a case-by-case basis, while adding that if a reverse payment agreement attempts to manipulate the 180-day exclusivity period, it is presumptively anticompetitive.[249] If such manipulation is found, the Court

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243. *See id.* (explaining that market entry by the first generic manufacturer reduces the price by five percent, but the second generic manufacturer to enter the market reduces the price by fifty percent).

244. *See id.* (explaining consumers saved eight to ten billion dollars in 1994 when generic manufacturers entered the market).

245. *See In re K-Dur*, 686 F.3d at 217 (arguing that reverse payment agreements are good policy for pharmaceutical manufacturers, but bad for consumers).

246. *See* Hemphill, *supra* note 21, at 1622-23 (requesting Congress provide clear guidance to the court in reverse payment agreements).

247. *See* FTC v. Actavis, Inc., 133 S.Ct. 2223, 2238 (2013) (holding the rule of reason was the appropriate analysis); *In re K-Dur*, 686 F.3d at 210-14 (noting that the D.C. Circuit has applied rule of reason, the Sixth Circuit applied per se designation, and the Eleventh, Second, and Federal Circuits applied the scope of the patent analysis).

248. *See Actavis*, 133 S.Ct. at 2237 (concluding the anticompetitive effect of a reverse payment agreement depends on individual factors regarding the payment); Broad. Music, Inc. v. Columbia Broad. Sys., Inc., 441 U.S. 1, 19 (1979) (concluding the rule of reason applies to license monopolies because the agreement could have procompetitive benefits in the context of the legal monopoly created by copyright laws).

249. *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1339 (Fed. Cir. 2008) (concluding that manipulating the 180-day exclusivity period typically results in a bottleneck on the generic market entry and is a violation of Sherman Act).

should then apply the per se illegal analysis because experience has proven that asserting the 180-day manipulation while refraining to market the generic drug is an unreasonable restraint to trade.[250] As a result, clear antitrust law to antitrust claims against reverse payment agreements can be established.[251]

250. *See In re K-Dur*, 686 F.3d at 218 (calling for a rule of reason analysis that can be rebutted by showing the payment was not for market delay, or that a pro-competitive benefit stems from the agreement).

251. *See* United States v. Singer Mfg. Co., 374 U.S. 174, 196-97 (1963) (explaining that possessing a valid patent does not make the patent holder exempt from the Sherman Act beyond the patent's monopoly limits, and there are strict limitations on concerted efforts regarding a patent).